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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

HM22/0323

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PATENT: P  
ART UNIT PAPER NUMBER

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DATE MAILED:

03/23/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/601,019	Applicant(s) Bordighera, M. R.
Examiner Patricia Patten	Group Art Unit 1651

Responsive to communication(s) filed on \_\_\_\_\_.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-20 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s) ✓

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Claim Objections***

Claims 4 and 11 are objected to because of the following informalities:

Claim 4 recites 'concentration of caffeine of between....', which should correctly read 'concentration of caffeine is between....'.

Claim 11: 'weigh' should properly read 'weight.'

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-20 recite the term 'extract.' This term is deemed indefinite in that the meets and bounds of the claim are undefined. There are many extracts which could be performed on green tea, however, every extract would necessarily produce different compositions having various phytochemical constituents. Because of the varying nature of the final product, it is crucial to the definiteness of the claim that the type of extraction procedure precede the term 'extract'; ie, methanol extract, or ethanol extract in order to avoid confusion.

Claim 5 recites a composition, however contains functional language. The functional language in the claim is indefinite in that it does not materially change the composition. Further, the language 'so as to allow the' is indefinite in that the meets and bounds of the term 'to allow' is not clearly delineated. Is the composition administered in the claimed doses, or is it not?

Clarification is needed.

Claims 6-10 and 17-18 recite, or depend upon a claim which recites in the preamble; 'A method of manufacturing' however, do not contain steps for manufacturing. For example, Claim 6 recites 'comprising using an extract or powder of green tea.' This term lacks antecedent basis in the claim in that the preamble merely recites a method for manufacture, not a method for treating. Further, claims 7-10 do not recite functional language in the claims which render the claims indefinite because the preamble of the claims recite a method. Thus, Claims 7-10 also lack antecedent basis in Claim 6. Correction is necessary.

Claims 11-15 and 19-20 are vague and indefinite in that they recite, or depend upon a claim which recites 'A method for the esthetic treatment of a human being in order to enhance his

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or her figure.' The phrase 'enhance his or her figure' is vague in that 'enhance' is not clearly defined, and could have different meanings in the art. 'Enhance' is not proportional to weight loss, and therefore the claim is confusing. Further, the term 'which is as low as desired' is deemed indefinite because the meets and bounds of the phrase are not clearly delineated.

Correction is necessary.

Claims 12-15 lack antecedent basis in claim 11 because the claims do not provide for any functional language. Hence, the claims do not properly limit the base claim which is a method claim. Alternatively, the claims merely state inherent properties of the composition, or wherein the extract is titrated. It is suggested that Claim 15 recite; 'A method according to Claim 11....wherein said oral administration comprises administration of a daily dose of green tea from 250 mg to 500 mg...' in order to avoid confusion.

Claim 15 recites 'administration of a daily dose...'. This phrase is confusing because the term 'daily dose' is unclear. It is suggested that "daily dose" be further clarified by adding 'green tea' after the term as displayed *supra*.

Claim 16 is indefinite in that it does not properly limit claim 5 which is a composition claim. Claim 16 merely recites functional language which lacks antecedent basis in claim 5. Correction is necessary.

Claims 19 and 20 also recite inherent properties of the composition, wherein the claims are dependant upon a base claim which recites a method. Thus, the claims do not further limit the method in that they do not contain any functional language.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hara (US 4,673,530). Claims 1-10 and 16-18 are drawn to a composition comprising an extract of green tea containing from 20-50% by mass of catechols expressed as epigallocatechol gallate (EGCG). Claims are further drawn to where the extract of green tea contains from 5-10% by mass of caffeine, wherein the ratio of the concentration of catechols to caffeine is between 2 and 10, wherein the extract of green tea is titrated to allow a daily administration. Claims 6-10 are further drawn to a method of manufacturing the medicament.

Hara (US 4,673,530) disclosed processes for producing antioxidant activities via extraction of green tea (Abstract). Hara proposed numerous extraction techniques of green tea including aqueous/methanol (Col. 4, Examples 3 and 4), aqueous/ethanol (Col. 1, Example 2), aqueous/acetone (Col. 4, Example 5) and pure solvent extractions without water (Please see Tables 2 and 3). Hara taught that all of the extracts contained tannins in the form of epigallocatechin gallate as well as smaller amounts of epigallocatechin, epicatechin gallate and

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epicatechin (Col.2, lines 44-55). Specifically, Hara taught that the tannin content was usually about 30% to about 70%, depending upon the extraction protocol, and that the extract primarily composed epigallocatechin gallate (Col.2, lines 51-55). Examiner has deemed, although Hara did not state the EGCG concentration specifically, that 'primarily composed' means at least 50% or more, or at least 30% by weight of the entire tannins in the composition. Thus, it is deemed that the extractions performed by Hara all contained EGCG in amounts ranging from 20-50% if not more.

Hara did not specifically state the concentration of caffeine in the composition. However, Applicant performed a methanol extraction on the green tea and then quantitatively measured the amount of caffeine in said methanol extract. Hara also performed a methanol extraction (Table 2). Thus, this product also contained the claimed ranges of caffeine because it was inherent to the composition. Moreover, the ranges claimed for EGCG were also inherent properties of a known composition (although they were also deemed anticipated-*supra*):

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Thus, it is deemed that the composition was known, based on the teachings of Hara, especially absent clear, credible evidence to the contrary.

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The language ‘for the curative and prophylactic treatment of obesity’ is merely an intended use of a product which was already known in the art. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). “When the claim recites using an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is anticipated” (MPEP 2100 pp. 2113).

Claims 6-10 and 17-18 recite methods for the manufacture of a medicament, however, do not propose any method steps for the manufacture (Please see 35 U.S.C. 112 Second paragraph rejections *supra*). Thus, any preparation for the manufacture of an extract of green tea anticipates these claims. Because Hara specifically taught that tannins were natural antioxidants and proposed numerous extraction methods to obtain tannins from green tea, this certainly anticipates any claim to a method for manufacture which does not recite any method steps besides ‘use of the extract’ or inherent properties of the extract such as the catechol percentages.

Claims 11- 15 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuchi et al. (JP 60114153- Abstract). Claims 11-15 and 19-20 are drawn to a method for treating a human in order to enhance his or her figure via oral administration of a catechol-enriched extract of green tea.

Yuchi et al. (JP 60114153- Abstract) disclosed that an aqueous/acetone extract of green tea had a beneficial effect on obesity. The extract was further treated with chloroform and ether. Yuchi et al. were not specific as to the EGCG content, however, because their extraction procedure very closely resembled the aqueous/acetone extraction proposed by Hara, it is deemed

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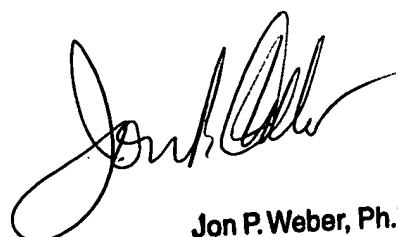
that their green tea extract also contained abundant catechols. However, where claims state inherent properties of a composition, and when such a claim is dependant upon a base method claim, the mere statement of an inherent property does not materially change the method, and holds no patentable weight (Please see 35 U.S.C. 112 Second Rejections-*supra*).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.  
Primary Examiner